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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER M. BONUTTI

Appeal 2007-4107
Application 10/662,923
Technology Center 3700

Decided: June 26, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an apparatus for separating tissue layers. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification describes a retractor including "a fluid-operated portion such as a balloon or bladder to retract tissue" (Spec. 3:8-9). The Specification also describes using "a pair of retractors . . . together to create a working space" (*id.* at 19:14-15). In addition, the Specification describes passing the leading end of a scope through the retractor into the working space (*id.* at 15:15-17).

Claims 2-5, 7-9, and 11-13 are pending and on appeal. Except for claim 13, the claims subject to each rejection have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claims 2 and 13, which are representative and read as follows:

2. An apparatus for separating layers of tissue comprising:

a first tubular member having an open proximal end and an open distal end defining a first bore therethrough;

a first inflatable member disposed on the distal end of the first tubular member, the first inflatable member having an uninflated state and an inflated state wherein the first inflatable member has an open proximal end and an open distal end defining a first aperture therethrough, the first aperture and the first bore being configured and dimensioned for receiving a surgical instrument therethrough;

a second tubular member having an open proximal end and an open distal end defining a second bore therethrough, the second tubular member being configured and dimensioned for receiving the first tubular member and the first inflatable member in the uninflated state; and

a second inflatable member disposed on the distal end of the second tubular member, the second inflatable member having an uninflated state and an inflated state, wherein the first and second inflatable members are longitudinally spaced apart to define a working space therebetween, and when the first and second members are in the inflated state, movement of the

first inflatable member towards the second inflatable member is capable of capturing body tissue therebetween.

13. The apparatus of claim 2, wherein movement of the first tubular member towards the second tubular member being capable of separating a first layer of body tissue from a second layer of body tissue when the first and second inflatable members are in the inflated state.

Claims 2, 5, 7-9, and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over Daniels (US 4,655,746, Apr. 7, 1987) in view of Kontos (US 5,180,367, Jan. 19, 1993) (Ans. 3). Claims 3 and 4 stand rejected under 35 U.S.C. § 103(a) as obvious over Daniels in view of Kontos and Evard (US 4,981,478, Jan. 1, 1991) (*id.* at 5). Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as obvious over Daniels in view of Kontos and Mecca (US 4,690,140, Sep. 1, 1987) (*id.* at 6).

The Examiner relies on Daniels for disclosing "first tubular member 68 having an open proximal end, first inflatable member 72, second tubular member 16 having an open proximal end and an open distal end defining a bore 18 therethrough . . . and second inflatable member 30" (Ans. 3). The Examiner relies on Kontos for teaching "that the tubular member of the inner, pilot balloon can have an open distal end so that it can slidably receive the guidewire instead of being fixed to the guidewire" (*id.* at 3-4). The Examiner relies on Evard and Mecca for features of claims that depend from claim 2 (*id.* at 5-6).

The Examiner finds:

> One of the advantages of having a catheter slidable on a guidewire as opposed to being fixed to the guidewire is . . . [i]f, after the guidewire and catheter (which is slidable on the guidewire) have been inserted into the body, it is determined that a different catheter (e.g. one with a different sized balloon)

> is needed, the guidewire may remain in the body while the catheter is replaced. The insertion of the second catheter over the guidewire is relatively quick and easy because the path to the target site has already be[en] made and is maintained by the pre-inserted guidewire.

(*Id.* at 4.) The Examiner concludes that it "would have been obvious to make the distal end of the first inflatable member 72 and first tubular member 68 of Daniels . . . open so that they can slidably receive a guidewire so that it too would have this advantage" (*id.* at 4-5).

The Examiner also finds that "[m]ovement of the first inflatable member 72 towards the second inflatable member 30 is inherently capable of capturing body tissue therebetween" (*id.* at 5). In addition, the Examiner finds that "the Daniels balloons can be first inflated and then one balloon can be moved toward the other balloon to separate tissue" (*id.* at 9-10).

Appellant contends that the Examiner erred in concluding that claims 2 and 13 would have been obvious over Daniels and Kontos.

ISSUES

The issues are whether Appellant has shown that the Examiner erred in concluding that claims 2 and 13 would have been obvious over Daniels and Kontos.

FINDINGS OF FACT

1. Daniels describes a catheter device that "includes a first catheter having a tube with distal and proximal ends, an inflatable balloon carried on the distal end of the tube, a channel extending through the tube, and a fluid conduit for supplying fluid to the balloon" (Daniels, col. 2, ll. 10-14).

2. Daniels also describes a "second catheter in the device also [having] a tube with distal and proximal ends, an inflatable balloon carried at the tube's distal end, and a fluid conduit for supplying fluid to the balloon" (*id.* at col. 2, ll. 15-18).

3. Daniels states that a "central region of the tube [of the second catheter] . . . is slidably carried within the channel of the first-catheter tube, to allow relative axial shifting of the tubes, to place the two balloons in the device a selected axial distance from one another" (*id.* at col. 2, ll. 19-23).

4. In particular, Daniels describes a second catheter including tube 68 with central bore 70 extending therethrough and inflatable balloon 72 "formed integrally with the walls of the tube" (*id.* at col. 4, ll. 28-42).

5. Daniels also describes a "guide wire **74** extending through the bore in tube **68** [that] is used to guide the tube . . . into a blood vessel" (*id.* at col. 4, ll. 52-56).

6. Daniels states that this guide "wire is attached at its distal end to a flexible spring **76**, which in turn is secured in the end of bore **70**. . . . Thus, the wire is securely anchored to the distal end of the tube **68** but can otherwise twist or rotate with respect to the tube along the tube's length." (*Id.* at col. 4, ll. 54-59.)

7. Kontos describes a system in which a pilot catheter is inserted in the vascular system to begin the enlarging process. Thereafter, the pilot catheter "remain[s] resident in the vascular system . . . while feeding [a] second, larger diameter . . . catheter over the pilot catheter." (Kontos, col. 1, l. 47, to col. 2, l. 57.)

8. Kontos describes a pilot catheter having an inflatable balloon membrane at or near its distal end (*id.* at col. 4, ll. 53-56).

9. Kontos states that the application of fluid under pressure causes the balloon membrane to expand (*id.* at col. 4, ll. 64-68).

10. Kontos also describes using "an indwelling guide wire **72** to facilitate placement of the pilot catheter" (*id.* at col. 8, ll. 8-10).

11. To utilize an indwelling guide wire, Kontos describes using a catheter having a guide wire lumen (*id.* at col. 8, ll. 10-13).

12. Kontos states that the "insertion of the guide wire can precede insertion of the pilot catheter, the two can be inserted together as a unit, or the guide wire can be inserted after the pilot balloon is in the vascular system, all in accordance with well known techniques" (*id.* at col. 8, ll. 15-19).

13. Based on how the guide wire may be used with the pilot catheter, the guide wire lumen must have a distal opening (*id.* at Fig. 9; Ans. 3-4; Br. 7).

ANALYSIS

Daniels describes a catheter having a guide wire that is secured to a tube of the catheter at the distal end (Findings of Fact (FF) 1-6). Kontos describes a catheter including a guide wire lumen having a distal opening for receiving a guide wire (FF 8-13). We agree with the Examiner that it would have been obvious to modify Daniels' catheter to include a guide wire lumen having a distal opening, as described in Kontos, to permit the use of a guide wire that is separate from the catheter.

Appellant argues, however, that "modifying the inner inflatable balloon of Daniels to have an open distal end as disclosed in Kontos has no reasonable expectation of success" (Br. 7). Specifically, Appellant argues:

> Modifying the inner inflatable balloon of Daniels to have an open distal end as disclosed in Kontos would necessitate the removal of the flexible spring that would eliminate a pressure boundary for the inflatable balloon and the attachment point for the guide wire. Without a pressure boundary at its distal end, the inner inflatable balloon would be incapable of retaining pressurized fluid and would not inflate upon introduction of the pressurized fluid. In addition, without an attachment point for the guide wire, the inner inflatable balloon would not rotate when the guide wire is rotated from the manifold. This modification, as proposed by the Examiner, renders the catheter disclosed in Daniels inoperable for its intended purpose.

(*Id.* at 8.)

We are not persuaded by this argument. Kontos describes an inflatable member that has an open distal end and that inflates upon introduction of pressurized fluid (FF 8, 9, & 13). Therefore, as noted by the Examiner, "[m]aking the distal end of the balloon 72 of Daniels et al. open to slidably receive a guidewire as taught by Kontos . . . would not prevent the balloon from retaining pressurized fluid since the balloon itself would be sealed while the guidewire lumen passing through the balloon would have an open distal end" (Ans. 7).

In addition, Appellant has not adequately explained why the failure of the inner inflatable balloon to rotate when the guide wire is rotated from the manifold would render Daniels' device inoperable for its intended purpose. In particular, Appellant has not explained why the Examiner is incorrect in

his position that "rotation of the balloon is not necessary for the guiding of the assembly into the body" (Ans. 9).

Appellant additionally argues that "Daniels fails to teach or suggest moving an inflated balloon towards another inflated balloon to capture tissue therebetween and separate a first layer of tissue from a second layer of tissue as recited in claim 13" (Br. 11-12). In particular, Appellant argues that "Daniels fails to disclose or suggest that either of the inflatable balloons should be moved when in the inflated state" (*id.* at 10-11). In fact, Appellant argues that "[m]oving one inflatable balloon towards the other inflatable balloon would be contrary to Daniels' disclosure about providing a hemostatic seal with the vessel" (*id.* at 11).

We are not persuaded by this argument. Claims 2 and 13 are each directed to an apparatus. Claim 2 requires that movement of the inflatable members be capable of capturing body tissue. Claim 13 additionally requires that movement be capable of separating body tissue.* However, being apparatus claims, claims 2 and 13 do not require that the inflatable members be moved. Thus, the applied references need not teach or suggest moving the inflatable members to render apparatus claims 2 and 13 obvious.

We conclude that the Examiner has set forth a prima facie case that claims 2 and 13 would have been obvious over Daniels in view of Kontos, which Appellant has not rebutted. We therefore affirm the rejection of

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* Claim 13 recites "movement of the first *tubular* member towards the second *tubular* member" (emphasis added). However, in view of Appellant's argument, it appears that he may have intended to refer to movement of the first *inflatable* member towards the second *inflatable* member.

claims 2 and 13 under 35 U.S.C. § 103(a). Claims 5 and 7-9 fall with claim 2.

Claims 3, 4, 11, and 12 directly or indirectly depend from claim 2. Appellant does not argue that claims 3 and 4 would not have been obvious over Daniels in view of Kontos and Evard or that claims 11 and 12 would not have been obvious over Daniels in view of Kontos and Mecca (Br. 4). We therefore affirm the rejections of these claims under 35 U.S.C. § 103(a).

CONCLUSION

The Examiner's position is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 2-5, 7-9, and 11-13 under 35 U.S.C. § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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